

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

WALTER SHUKER, et al.	:	CIVIL ACTION
	:	
v.	:	No. 13-6158
	:	
SMITH & NEPHEW PLC, et al.	:	

MEMORANDUM

Juan R. Sánchez, J.

September 29, 2016

Defendant Smith & Nephew, Inc. (S&N) asks this Court to dismiss Plaintiffs Walter and Vivian Shuker’s Third Amended Complaint asserting state-law claims for negligence, fraud, and loss of consortium arising out of S&N’s alleged “off-label” promotion of an artificial hip component used in Mr. Shuker’s hip replacement surgery.¹ In a prior opinion, this Court concluded that because the component in question—the R3 metal liner—was part of a device that the FDA had authorized S&N to market pursuant to the agency’s rigorous premarket approval process, Plaintiffs’ claims challenging the safety and effectiveness of the liner were preempted by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), except insofar as the claims were based on state tort duties that “parallel” the manufacturer’s duties under federal law. The Court further concluded that insofar as Plaintiffs’ Second Amended Complaint asserted such nonpreempted parallel claims, the claims were inadequately pleaded. The Court therefore dismissed the Second Amended Complaint in its entirety, granting Plaintiffs leave to amend, but only as to their parallel claims based on off-label promotion. Upon review of Plaintiffs’ Third Amended Complaint, the Court agrees with S&N that Plaintiffs’ efforts to plead a nonpreempted parallel claim based on off-label promotion are

¹ Off-label promotion of a medical device means promotion of the device for a use for which the Food and Drug Administration (FDA) has not approved it.

again unavailing. Accordingly, S&N's motion to dismiss will be granted and the Third Amended Complaint will be dismissed with prejudice.

FACTS²

S&N designs, manufactures, and sells the R3 Acetabular System (R3 System), a hip replacement system consisting of four parts: (1) an acetabular shell, (2) a liner for the shell, (3) a femoral head, and (4) a femoral stem. The R3 System is a Class II device which S&N received authorization to market in the United States pursuant to what is known as the § 510(k) process. Under that process, the FDA may permit a manufacturer to market a device if, after a limited review, the agency concludes the device is substantially equivalent to a preexisting device. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). The liner approved for use as part of the R3 System is made of cross-linked polyethylene (XLPE).

S&N received § 510(k) clearance to market the R3 System in June 2007, and on March 6, 2008, the company announced the launch of the System at the annual meeting of the American Academy of Orthopaedic Surgeons, touting it as “an advanced multi-bearing acetabular cup system used in total hip replacement procedures.” TAC ¶ 69 (emphasis omitted). S&N promoted the R3 System as safe, effective, and more beneficial to patients than other hip

² Except where otherwise specifically noted, the following facts are drawn from Plaintiffs' Third Amended Complaint, the well-pleaded factual allegations of which this Court must accept as true in evaluating the instant motion to dismiss. *See Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The Third Amended Complaint is cited herein as “TAC ¶ ____.” On a motion to dismiss, a court may consider, in addition to the complaint itself, any “exhibits attached to the complaint, matters of public record, [and] undisputedly authentic documents if the complainant's claims are based upon these documents.” *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010). Because Plaintiffs' claim that S&N engaged in off-label promotion is based in part on press releases the company issued in February 2009 and March 2008, the Court has considered the press releases, which are part of the record in this case, in evaluating S&N's motion to dismiss. *See* S&N's Opp'n to Pls.' Mot. for Leave to File Second Am. Compl. Ex. A (February 27, 2009, press release); Pls.' Opp'n to Smith & Nephew plc's Mot. to Dismiss Ex. F (March 6, 2008, press release).

replacement systems, describing it as “a high performance option that fits nicely into our growing portfolio of products for active patients.” *Id.* ¶¶ 71-72.

S&N also designs, manufactures, and sells the Birmingham Hip Resurfacing (BHR) System, a hip resurfacing system consisting of two main parts, both made of metal: (1) an acetabular component, i.e., a socket in the shape of a shallow cup, and (2) a femoral resurfacing component.³ The BHR System is a Class III device which the FDA authorized S&N to market based on the substantially more rigorous premarket approval (PMA) process, whereby approval is granted only if the FDA finds, after reviewing extensive application materials and data from the manufacturer, “there is a ‘reasonable assurance’ of the device’s ‘safety and effectiveness.’” *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-18 (2008) (quoting 21 U.S.C. § 360e(d)). The BHR System received premarket approval in May 2006, and in April 2007, S&N filed a PMA supplement seeking approval for a two-piece version of the acetabular component consisting of a metal acetabular shell and a metal liner. The FDA approved S&N’s PMA supplement in November 2008. The metal liner component of the two-piece acetabular component that received premarket approval as part of the BHR System is known as the R3 metal liner.⁴

³ A hip replacement procedure differs from a hip resurfacing procedure in that, in a hip replacement, the patient’s femoral head is removed and replaced with an artificial femoral head, whereas in a hip resurfacing, the damaged femoral head is covered with the femoral component of the device.

⁴ Although the R3 metal liner has never been approved for use with the R3 System in total hip replacements in the United States, the liner was approved for such use in Europe and Australia. *See Shuker v. Smith & Nephew plc*, No. 13-6158, 2015 WL 1475368, at *15 (E.D. Pa. Mar. 31, 2015); *cf.* TAC ¶¶ 102 (referring to data from Australian and United Kingdom patient registries regarding the performance of the R3 metal liner within the R3 System).

In February 2009, approximately a year after launching the R3 System for use in total hip replacement procedures, S&N issued a press release announcing the introduction of a “metal liner option” for the System, which provided, in relevant part:

Memphis, Tenn. (February 27, 2009) – Smith & Nephew, Inc. (NYSE: SNN, LSE: SN) Orthopaedic Reconstruction & Trauma today announced the introduction of a metal liner option for its R3 Acetabular System, an advanced multi-bearing acetabular cup system used in hip replacement and resurfacing procedures.

The metal liner was recently approved by the Food and Drug Administration for use with the BIRMINGHAM HIPTM Resurfacing (BHRTM) system. Since March 2008, the R3 system has been fitted with cross-linked polyethylene (XLPE) liners for use in total hip replacement cases, and Smith & Nephew this week received FDA approval of its ceramic liner option. It is the only acetabular system available to surgeons that accommodates the major advanced bearing options, including metal-on-metal, ceramic-on-ceramic, cobalt chrome on cross-linked polyethylene (XLPE), and the company’s exclusive OXINIUMTM Oxidized Zirconium on XLPE.

S&N’s Opp’n to Pls.’ Mot. for Leave to File Second Am. Compl. Ex. A. S&N used the February 2009 press release to promote its products and expected the press release to reach surgeons who use its products, like Dr. Terefenko, Mr. Shuker’s surgeon. Dr. Terefenko either read the February 2009 press release or was aware of its claims.

In April 2009, approximately two months after the metal liner was introduced, Mr. Shuker underwent total hip replacement surgery, in which Dr. Terefenko used the R3 metal liner with components of the R3 System, resulting in a metal-on-metal articulation between the femoral head of the R3 System and the R3 metal liner. Because the metal liner was not approved for use with the R3 System, Dr. Terefenko’s use of the liner was an “off-label” use.

Approximately 21 months after surgery (around January 2011), Mr. Shuker began developing discomfort in his buttocks, groin, and thigh, causing him pain and limiting his daily activities. In May 2011, he underwent an aspiration procedure, which produced milky brown

tinged fluid and metallic debris, which was removed. Based on the procedure, Dr. Terefenko determined Mr. Shuker's pain was caused by metal sensitivity due to the degeneration of the metal-on-metal articulation of the hip components, and recommended replacement of the metal-on-metal articulation to relieve the pain. In July 2011, Mr. Shuker underwent another surgery in which Dr. Terefenko replaced the metal-on-metal articulation with an Oxinium femoral head component and a polyethylene liner.

In June 2012, approximately eleven months after Dr. Terefenko replaced the R3 metal liner used in Mr. Shuker's surgery, S&N announced the company was initiating "a voluntary withdrawal of the optional metal liner component of its R3 Acetabular System." TAC ¶ 96 (emphasis added); *see also id.* ¶ 101. S&N explained the withdrawal was a "precautionary measure" based on data—including data from Australian and United Kingdom patient registries—indicating the metal liner was not performing as well as the company would like "within the R3 Acetabular System." *Id.* ¶ 102. The same month, the Medicines and Healthcare Products Regulatory Agency, the United Kingdom's analogue to the FDA, advised surgeons to stop using the R3 metal liner based on findings that the revision rate for the liner was higher than for non-metal liners and also exceeded the "4% guidance figure at four years from National Institute of Health and Clinical Excellence." *Id.* ¶ 104. The agency also advised surgeons to annually monitor the 281 patients who had been fitted with metal liners "so that any complications such as pain or swelling are picked up and treated early." *Id.*

Following his July 2011 surgery, Mr. Shuker again developed extreme pain in his right hip for which he sought treatment in November 2012. Dr. Terefenko performed another aspiration procedure and determined Mr. Shuker had developed an infection at the site of the surgery. A month later, another surgeon, Paul Pollice, M.D., performed an explant of the hip

replacement to remove the R3 System for eventual replacement, and in January 2013, Mr. Shuker underwent another total hip replacement surgery to replace the R3 System.

Plaintiffs allege—citing the February 2009 press release regarding the R3 metal liner and the liner’s name, which directly associates it with the R3 System—that S&N “actively marketed the metal liner as ‘optional’ for the R3 Acetabular System, especially for more active patients like Mr. Shuker,” and in a way that led surgeons like Dr. Terefenko to believe the liner was a component of the R3 System and was safe to use with the R3 system. *See* TAC ¶¶ 81-82, 86, 88-89, 92-93. Plaintiffs further allege such marketing influenced Dr. Terefenko to use the liner off-label in Mr. Shuker’s hip replacement surgery. *Id.* ¶¶ 85-94. Despite S&N’s claims, “the R3 acetabular system was prone to wearing down and releasing metallic debris into the body of the user causing adverse health effects including, but not limited to: bone chipping, bone fractures, tissue damage, chronic pain, metalosis, and the need for ‘revision’ surgery to replace entirely the R3 Acetabular system.” *Id.* ¶ 100.

Plaintiffs seek to hold S&N liable for injuries Mr. Shuker sustained as a result of Dr. Terefenko’s off-label use of the R3 metal liner in his hip replacement surgery, asserting a negligence-based claim for “tortious misconduct based on off-label promotion” and a fraud claim. Plaintiffs also bring a claim for loss of consortium on behalf of Mrs. Shuker.

For their negligence claim, Plaintiffs allege S&N breached its duty to use reasonable care in promoting its products by making misleading or inaccurate statements in the course of promoting the R3 metal liner for off-label use and by failing to provide adequate warnings about such off-label use. Plaintiffs further allege had S&N not promoted the R3 metal liner’s use with R3 System, Dr. Terefenko would not have chosen—and Mr. Shuker would not have consented to implantation of—the device components used in his hip replacement surgery.

For their fraud claim, Plaintiffs allege S&N “willfully concealed, misrepresented, suppressed and omitted material scientific and medical information” about the risks of the off-label use. *See* TAC ¶ 146. Plaintiffs further allege Mr. Shuker and Dr. Terefenko reasonably relied on S&N’s false and incomplete statements and omissions in selecting the components to use in Mr. Shuker’s hip replacement surgery in 2009 and/or in leaving those components in place until July 2011, even though Mr. Shuker began to show symptoms of metal toxicity months earlier.

DISCUSSION

To withstand a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Iqbal*, 556 U.S. at 678 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the facts pleaded “allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Id.* Although the plausibility standard “is not akin to a ‘probability requirement,’” the complaint must support “more than a sheer possibility that a defendant has acted unlawfully.” *Id.* (citation omitted). A complaint which “pleads facts that are merely consistent with a defendant’s liability . . . stops short of the line between possibility and plausibility of entitlement to relief.” *Id.* (quoting *Twombly*, 550 U.S. at 557) (internal quotation marks omitted). In evaluating a complaint’s sufficiency under these standards, the court must first “tak[e] note of the elements a plaintiff must plead to state a claim.” *Santiago v. Warminster Twp.*, 629 F.3d 121, 130 (3d Cir. 2010) (quoting *Iqbal*, 556 U.S. at 675). Next, the court should “identify allegations that, ‘because they are no more than conclusions, are not entitled to the assumption of truth.’” *Id.* (quoting *Iqbal*, 556 U.S. at 679). Finally, where there are well pleaded allegations, the court

“should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief.” *Id.* (quoting *Iqbal*, 556 U.S. at 679).

Based on this Court’s earlier preemption ruling, Plaintiffs are limited to pursuing so-called “parallel” claims based on S&N’s alleged off-label promotion of the R3 metal liner for use in total hip replacements as part of the R3 System.⁵ As explained in the prior ruling, a parallel claim is a claim for a violation of a state-law duty that is parallel to (or narrower than) a duty imposed under federal law. Such a claim avoids express preemption because the MDA preempts only those state law requirements relating to the safety or effectiveness of a device which are “different from, or in addition to,” the requirements applicable to the device under federal law, 21 U.S.C. § 360k(a), but does not prevent a state from “provid[ing] a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements,” *Lohr*, 518 U.S. at 495; *see also Riegel*, 552 U.S. at 330. Although a nonpreempted parallel claim must be premised on a violation of federal law, the claim cannot exist “solely by virtue of [federal law],”

⁵ In opposing S&N’s motion to dismiss, Plaintiffs urge this Court to reconsider its preemption ruling in light of the decisions in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736 (S.D. W. Va. 2014), and *Edwards v. Ethicon, Inc.*, 30 F. Supp. 3d 554 (S.D. W. Va. 2014), in which the district court rejected a manufacturer’s argument that claims concerning a medical device cleared via the § 510(k) process were preempted by the MDA because a component of the § 510(k)-cleared device had received premarket approval. This Court considered the rulings in *Huskey* and *Edwards* in addressing the preemption issue in this case and found those rulings distinguishable for the reasons set forth in the Court’s prior opinion regarding preemption. *See Shuker*, 2015 WL 1475368, at *9 n.17. Plaintiffs do not address this Court’s analysis of these rulings and have thus provided no basis for the Court to reconsider its earlier ruling on this issue.

Plaintiffs also urge the Court to reconsider its holding that they must plead a parallel claim to avoid express MDA preemption, arguing S&N forfeited any preemption protection to which it would otherwise be entitled by promoting the R3 metal liner for use off-label with the R3 System. In support of this argument, Plaintiffs again cite *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977 (D. Ariz. 2013), a decision this Court considered but declined to follow in its earlier preemption ruling. *See Shuker*, 2015 WL 1475368, at *10 n.19. The Court is not persuaded reconsideration of its earlier ruling is warranted and therefore will adhere to its holding that off-label promotion is “a possible basis for a parallel claim, rather than a wholesale exemption from preemption.” *Id.*

lest it conflict with the FDCA's remedial scheme, which leaves enforcement of the statute's requirements to the Federal Government. *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 352-53 (2001) (holding state law fraud-on-the-FDA claims that "exist[ed] solely by virtue of the FDCA disclosure requirements" conflicted with and were therefore impliedly preempted by the FDCA). Thus, to avoid implied preemption, the claim must also be grounded in "traditional state tort law." *Id.* at 353.

Here, Plaintiffs attempt to ground their claims in traditional state tort law, asserting a negligence-based claim for "tortious misconduct based on off-label promotion" and a fraud claim. To state a claim for negligence, a plaintiff must "establish the breach of a legally recognized duty or obligation that is causally connected to the damages suffered by the complainant."⁶ *Bilt-Rite Contractors, Inc. v. The Architectural Studio*, 866 A.2d 270, 280 (Pa.

⁶ Plaintiffs allege Pennsylvania law imposes on a device manufacturer "a duty to use reasonable care in the way it promotes its products to avoid being misleading and/or inaccurate." TAC ¶ 121. Although Plaintiffs do not cite any case law recognizing such a duty, the Pennsylvania Supreme Court has recognized negligent marketing as a viable theory of liability against a drug manufacturer in some instances. *See Lance v. Wyeth*, 85 A.3d 434, 458 (Pa. 2014) (holding a drug manufacturer may violate a duty of care in marketing by "tendering into the market a drug which it knows or should know is so dangerous that it should not be taken by anyone"); *Baldino v. Castagna*, 478 A.2d 807, 810 (Pa. 1984) (holding a drug manufacturer may breach a duty of reasonable care "by promoting its product in such a way as to nullify printed warnings"). In *Lance*, the Supreme Court specifically rejected a drug manufacturer's argument that "the only cognizable variant of negligent marketing [in Pennsylvania] is in the form of overpromotion," 85 A.3d at 460 n.38, and cited approvingly a statement by amici in the case that a "manufacturer's negligent conduct can occur at any stage of the marketing process," *id.* at 458. Given the Court's statements in *Lance*, and because S&N does not argue otherwise, the Court assumes the existence of the state law duty Plaintiffs allege.

The substance of Plaintiffs' tortious misconduct claim is that S&N made misleading or inaccurate statements in the course of promoting off-label use of the R3 metal liner, *see* TAC ¶ 125, and failed to warn physicians about the dangers of such off-label use, *see id.* ¶¶ 126-27. Insofar as the alleged failures to warn occurred independently of S&N's alleged off-label promotion—i.e., in the labeling and surgical technique brochure for the components of the R3 System, *see id.* ¶¶ 126-27—the Court fails to see how they amount to a breach of S&N's duty to use reasonable care in promoting its products. Rather, such allegations would appear to implicate a separate failure to warn claim. *See In re Avandia Mktg., Sales Practice & Prod.*

2005) (quoting *Sharpe v. St. Luke's Hosp.*, 821 A.2d 1215, 1218 (Pa. 2003)). The elements of a fraud claim are:

(1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance.

Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994). A fraud claim based on intentional non-disclosure (i.e., omissions) has the same elements, “except that in a case of intentional non-disclosure the party intentionally conceals a material fact rather than making an affirmative misrepresentation. *Id.* at 889 n.12.

In addition to alleging the elements of a state tort claim, to state a plausible parallel claim, a plaintiff must also allege the defendant’s tortious conduct violates federal law. Here, the federal law violation alleged is off-label promotion. Although the FDCA does not expressly prohibit device manufacturers from promoting off-label uses of their products, numerous courts have interpreted the statute’s prohibition on “misbranding” medical devices to encompass off-label promotion to varying extents. The FDCA expressly prohibits the misbranding of any device in interstate commerce as well as the introduction into interstate commerce of any misbranded device. 21 U.S.C. § 331(a), (b). A device is misbranded if its labeling⁷ is “false or

Liab. Litig., 639 F. App’x 874, 878 (3d Cir. 2016) (holding a drug manufacturer is subject to liability for failure to warn “where it ‘fails to exercise reasonable care to inform [the physician] of the facts which make the product likely to be dangerous’” and where, if “the manufacturer issued a proper warning to the plaintiff’s prescribing physician, the physician would not have prescribed the drug to the plaintiff and the injury would have been avoided” (alteration in original) (citations and internal quotation marks omitted)).

⁷ For purposes of the FDCA, the term “labeling” means “all labels and other written, printed, or graphic matter (1) upon an article or any of its containers or wrappers, or (2) accompanying such article.” 21 U.S.C. § 321(m).

misleading in any particular” or does not bear adequate directions for use, or, in the case of a restricted device,⁸ if “its advertising is false or misleading in any particular.” *Id.* § 352(a), (f), (q). FDA regulations also prohibit a manufacturer from advertising a device “in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.” 21 C.F.R. § 814.80.

Precisely how and to what extent off-label promotion violates these or other provisions of federal law is a matter of some debate in the federal courts. Because misbranding explicitly encompasses false and misleading advertising, numerous courts have concluded off-label promotion violates federal law when it is false and misleading. *See, e.g., Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1034-35 (D. Haw. 2014); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 702 (S.D. Tex. 2014); *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1179 & n.8 (C.D. Cal. 2013); *cf. United States v. Caronia*, 703 F.3d 149, 165 n.10 (2d Cir. 2012) (“Under 21 U.S.C. § 331(a), a defendant may be prosecuted for untruthfully promoting the off-label use of an FDA-approved drug, e.g., making false or misleading statements about a drug.”).

Courts have also interpreted the FDCA to prohibit *all* off-label promotion. One rationale for this view is that the FDA regulation prohibiting the advertising of a PMA-approved device in a manner inconsistent with any condition to approval specified in the PMA approval also prohibits a manufacturer from advertising a device for uses beyond those specified in the approval order. *See, e.g., Beavers-Gabriel*, 15 F. Supp. 3d at 1034-35; *Houston*, 957 F. Supp. 2d at 1179-80 & n.8; *cf. Carson v. Depuy Spine, Inc.*, 365 F. App’x 812, 815 (9th Cir. 2010) (suggesting the marketing and promotion of a Class III medical device for unapproved use

⁸ According to the PMA approvals for the BHR System and the modular BHR cup, of which the R3 metal liner is a part, the device is a restricted device for purposes of § 352(q). *See* Decl. of Gino Rouss in Supp. of Def.’s Mot. for Summ. J. Exs. A, B.

violates FDA regulations regarding off-label promotion and therefore “violates Section 331 of the FDCA”). Other courts endorsing this view have held off-label promotion causes a device to be misbranded because it evidences a new intended use of the device, for which the directions for use in the device labeling are inadequate.⁹ *See, e.g., Ramirez*, 961 F. Supp. 2d at 990 & n.7; *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 784 & n.8 (D. Minn. 2009).

In *United States v. Caronia*, the Second Circuit Court of Appeals declined to construe the FDCA’s misbranding provisions as prohibiting “the simple promotion of a drug’s off-label use,” finding such a construction would raise First Amendment concerns, at least where the off-label promotion was “not in and of itself false or misleading.” *See* 703 F.3d at 160-62, 165 & n.10. While the court rejected a construction of the FDCA under which “off-label promotion is tantamount to illegal misbranding,” it left open the possibility that off-label promotion could constitute evidence “of an intended use of a drug that the FDA has not approved” and thus of the drug’s mislabeling for that intended use. *See id.* at 155, 161-62; *see also U.S. ex rel. Polansky v.*

⁹ As noted, to avoid being misbranded, a device must be accompanied by labeling bearing “adequate directions for use.” 21 U.S.C. § 352(f). FDA regulations define the term “adequate directions for use” with reference to the intended use of the device, specifying “[a]dequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended.” 21 C.F.R. § 801.5. The “intended use” of the device depends, in turn, on the “objective intent of the persons legally responsible for [its] labeling,” and may include a purpose for which the device is “offered and used,” even if the device is not labeled or advertised for that purpose. *Id.* § 801.4. While prescription devices, which are safe for use only under medical supervision, are exempt from the requirement to provide “adequate directions for use,” the labeling for such devices must bear “information for use,” including information regarding “any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely *and for the purpose for which it is intended, including all purposes for which it is advertised or represented.*” *Id.* § 801.109(c) (emphasis added). Thus, promotion of an off-label use of either a prescription or a nonprescription medical device can evidence the intended use of the device and can thereby affect the disclosures that must be made in the device labeling so that the device is not misbranded. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1348-49 (10th Cir. 2015) (Lucero, J., dissenting).

Pfizer, Inc., 822 F.3d 613, 615 n.2 (2d Cir. 2016) (characterizing *Caronia* as leaving open “the government’s ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug’s FDA-approved label”).¹⁰

Citing *Caronia*, S&N argues that to state a viable parallel claim, Plaintiffs must allege facts plausibly showing S&N engaged in off-label promotion of the R3 metal liner that was false and misleading. Plaintiffs dispute this, asserting a manufacturer’s promotion of a device for use in a manner contrary to the use considered and approved by the FDA is inherently false and misleading. The Court need not resolve this issue. Even assuming all off-label promotion of a prescription medical device violates federal law, to state a parallel claim based on such a violation, a plaintiff must plausibly allege the defendant affirmatively promoted the particular off-label use of the device in question that caused the plaintiff’s injuries—here, that S&N affirmatively promoted the R3 metal liner for use with the R3 System in total hip replacement procedures. *See Riley*, 625 F. Supp. 2d at 784. Upon careful consideration of the Third Amended Complaint, the Court is not persuaded Plaintiffs have done so here.

Plaintiffs claim S&N promoted the R3 metal liner for off-label use in hip replacement procedures by marketing the liner as “optional” for the R3 System, a total hip replacement system. The principal basis for this claim is the February 2009 press release in which S&N announced “the introduction of a metal liner option for its R3 Acetabular System.” Although the

¹⁰ *Caronia* was a criminal case in which the defendant, a pharmaceutical sales representative, was convicted of conspiracy to introduce a misbranded drug into interstate commerce based on his promotion of the drug for off-label use. On appeal, the defendant argued his conviction violated his right of free speech under the First Amendment. Agreeing that the defendant had been convicted solely for his speech in promoting the off-label use of the drug, and that such a prosecution would run afoul of the First Amendment, the Second Circuit vacated the defendant’s conviction.

Third Amended Complaint refers to “materials” and “advertising” referring to an optional metal liner for the R3 System, the February 2009 press release is the only instance of such off-label promotion described in the Complaint.¹¹ Plaintiffs’ characterization of the press release as promoting the R3 metal liner for use in hip replacement procedures is based on a selective reading of only a portion of the release. When the press release is considered as a whole, it is apparent Plaintiffs’ strained interpretation is not reasonable.

In arguing the press release constitutes off-label promotion, Plaintiffs emphasize the first sentence of the release, which announces “the introduction of a metal liner option for [S&N’s] R3 Acetabular System, an advanced multi-bearing cup system use in hip replacement and resurfacing procedures.” Plaintiffs argue this statement, by referring to the metal liner as an “option” for the R3 System, “signal[ed] that the R3 metal liner was approved for use in hip replacement procedures, or at least that its use was perfectly safe.” Pls.’ Opp’n to Def.’s Mot. to Dismiss Pls.’ Third Am. Compl. 23. This argument ignores the fact that the press release characterizes the R3 System not solely as a hip replacement system, but as “an advanced multi-bearing acetabular cup system used in hip replacement *and resurfacing procedures*,” thereby disclosing that the System has multiple uses. The announcement of a metal liner option for the

¹¹ Insofar as Plaintiffs allege S&N “promoted the R3 metal system as a ‘revolutionary’ metal on metal system at the launch of the device,” TAC ¶ 124, this allegation is demonstrably false. As the Third Amended Complaint elsewhere alleges, S&N announced the launch of the R3 System in March 2008, a year before the R3 metal liner was introduced, *id.* ¶¶ 69-70, 76, and the press release announcing the launch makes no mention of “metal on metal.” The Complaint also references the surgical technique brochure for the R3 System, alleging the brochure, which is “part of an overall promotional effort,” does not “provide consumers information regarding the R3 metal liner’s unavailability in the United States nor clear references to the package insert for said device.” *Id.* ¶¶ 127-28. Plaintiffs do not suggest the surgical technique brochure affirmatively promoted the R3 metal liner for use in hip replacements. Indeed, this Court previously rejected that argument in its prior ruling in this case. *See Shuker*, 2015 WL 1475368, at *14 n.25.

System says nothing about the particular uses of the System for which the metal liner option is appropriate.

Moreover, the press release nowhere affirmatively recommends the metal liner for use in total hip replacement procedures, much less suggests the liner would be safe or appropriate for use in such procedures. To the contrary, it references the metal liner only in connection with hip resurfacing procedures, disclosing that the metal liner “was recently approved by the Food and Drug Administration for use with the BIRMINGHAM HIPTM Resurfacing (BHRTM) System.” Insofar as the press release discusses use of the R3 System in total hip replacements, it promotes only the System’s XLPE and ceramic liners for use in such procedures, specifying that “[s]ince March 2008, the R3 system has been fitted with cross-linked polyethylene (XLPE) liners for use in total hip replacement cases, and Smith & Nephew this week received FDA approval of its ceramic liner option.” Although the press release touts the R3 System as “the only acetabular system available to surgeons that accommodates the major advanced bearing options, including metal-on-metal, ceramic-on-ceramic, cobalt chrome on cross-linked polyethylene (XLPE), and the company’s exclusive OXINIUMTM Oxidized Zirconium on XLPE,” it nowhere suggests all of these options are appropriate for both hip replacement and hip resurfacing procedures. Because the press release makes clear that the acetabular cup system for which the R3 metal liner is an option is a system used in hip replacement and resurfacing procedures, and because it promotes the metal liner for use only with the company’s BHR System, a hip resurfacing device, Plaintiffs’ characterization of the press release as an instance of off-label promotion of the metal liner for use in hip replacement procedures is not reasonable.

Nor does the Third Amended Complaint otherwise plead facts that support a reasonable inference that S&N promoted the R3 metal liner for use in hip replacements. Plaintiffs point to

the liner's name—the R3 metal liner—as evidencing its “direct association with the R3 Acetabular System,” TAC ¶ 87, but the name alone says nothing about the manner in which S&N promoted the liner. Plaintiffs also allege Dr. Terefenko's treatment notes allude to S&N's off-label marketing, citing Dr. Terefenko's statement, “I believe given [Mr. Shuker's] body habitus and his activity level a metal-metal articulation is appropriate despite his age of 70 years. He is in full agreement and requests a large head metal-metal bearing. Specific risks as they relate to cardiac and renal issues were discussed at length with him and he has indicated his full understanding.” TAC ¶ 95. Contrary to Plaintiffs' suggestion, however, Dr. Terefenko's treatment note does not “contain[] language similar to that contained in [S&N's] promotions.” *See* Pls.' Opp'n to Def.'s Mot. to Dismiss Pls.' Third Am. Compl. 18. Indeed, as noted, the February 2009 press release does not recommend the metal liner for anything other than hip resurfacing procedures. Finally, Plaintiffs note that at the time S&N initiated its global recall of the metal liner, more metal liners had been used in hip replacements than in hip resurfacings. Notably, Plaintiffs do not specify whether this allegation pertains to the metal liner's domestic or global use pattern. Even assuming more metal liners were used in hip replacement than in hip resurfacing procedures in this country, this allegation is at most consistent with S&N's off-label promotion of the liner but stops short of a plausible showing that S&N acted unlawfully.

Because Plaintiffs' Third Amended Complaint fails to plead facts from which it can reasonably be inferred that S&N affirmatively promoted the R3 metal liner for off-label use in total hip replacement procedures, the Complaint fails to state a plausible parallel claim based on

off-label promotion. Accordingly, S&N's motion to dismiss the Third Amended Complaint will be granted.¹² An appropriate order follows.

BY THE COURT:

/s/ Juan R. Sánchez
Juan R. Sánchez, J.

¹² The dismissal also extends to Plaintiffs' loss of consortium claim, which is derivative of their parallel claims.